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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,816	08/25/2000	Michael R. Yeaman	660081.415C1	6324

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,816

Applicant(s)

YEAMAN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-79 is/are pending in the application.
- 4a) Of the above claim(s) 70-74 and 76-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67-69 and 75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 67-79 are pending.

Applicants' amendment filed on November 21, 2003 is acknowledged, and applicants' response has been fully considered. Claim 67 has been amended, and claims 70-74 and 76-79 are non-elected inventions, thus withdrawn from consideration. Therefore, claims 67-69 and 75 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 101

2. The previous rejection of claims 67-69 and 75 under 35 U.S.C. 101, is withdrawn in view of applicants' amendment of the claim, and applicants' response at page 4 in the amendment filed November 21, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 67-69 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 67-69 and 75 are indefinite because of the use of the term "mimetics thereof". The term "mimetics thereof" renders the claim indefinite, it is unclear what structures the mimetics have, and how different the mimetic is from the parent peptide. Claims 68, 69 and 75

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are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

In response, applicants indicate the term “mimetics thereof” is definite in view of the teachings in the specification, which discloses the invention peptide can be conformationally stabilized by replacing selected amino acid in the original peptide chain with amino acids that restrict the motion of the peptide chain, e.g., β -branched, N-methyl, α , β -dehydro, α , α -dialkyl and D- amino acids, and the substitutions with D- and other unusual amino acids into peptide templates can extend the half-life of the invention peptide (page 42, lines 12-21), and the skilled person would have understood with clarity that mimetics include peptidomimetics, peptoids or other peptide-like polymers or other non-polymeric compounds having functional groups that mimic a peptide as positioned (pages 4-6 of the response); regarding the art-knowledge, the manufacture of “peptidomimetics” was well known in the art, applicants submit the reference of Goodman and Ro as Exhibit A (Peptidomimetics for Drug Design, in “Burger’s Medicinal Chemistry and Drug Discovery” Vol. 1, pages 803-861), which describes representative types of peptidomimetics routinely prepared in the art including peptidomimetics that incorporate non-naturally occurring amino acids, peptidomimetics having modified linkages between consecutive residues, peptidomimetics in which a peptide bond is replaced with amide isosteres, transformations of secondary structure of peptides to nonpeptidic molecules, peptidomimetics that incorporate D-amino acids into the sequence (pages 6-7 of the response); and applicants also submit the reference of Cody et al. (J. Med. Chem. 40, 2228-2240 (1997)) as Exhibit B, which describes design and preparation of the Endothelin-A/Endothelin-B receptor antagonist PD156252, in which substitution of a single non-natural amino acid and N-methylation of the

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amide bond connecting two of the amino acid residues of the parent hexapeptide, thus, these results corroborate that the skilled artisan reading the specification would understand the scope of claim 67 with clarity as encompassing, e.g., non-natural amino acid or N-methylated amide bond incorporated into antimicrobial peptide (pages 7-8 of the response). The response has been considered, but the argument is not found persuasive because the specification at page 42, lines 12-21 describes “synthetic analogs” of selected peptides having antimicrobial activities (see page 42, line 9-12), not “mimetics” of the antimicrobial peptides, and the two references provided by the applicants also describe “peptidomimetics”, which is a subgroup of mimetics, as indicated in the applicants’ response (page 6, lines 1-3 of the response), the “mimetics” may include peptidomimetics, peptoids, other peptide-like polymers or other non-polymeric compounds having functional groups that mimic a peptide as positioned. However, neither the claim nor specification specifically define the term “mimetics thereof”, thus it is not clear what structures the mimetics would have.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 67-69 and 75 are rejected under 35 U.S.C. 102(b) as anticipated by Darveau *et al.* (U. S. Patent 5,409,898, April, 1995).

Darveau *et al.* disclose a cationic oligopeptide such as Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly which has α helical amphiphilic structure and

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antibacterial activity (column 12, lines 31-32 and 49-54), this peptide is the mimetic of SEQ ID NO:3 (Ala-Leu-Tyr-Lys-Lys-Phe-Lys-Lys-Lys-Leu-Leu-Lys-Ser-Leu-Lys-Arg-Leu-Gly; claims 67-69) or SEQ ID NO:9 (Ala-Leu-Tyr-Lys-Lys-Trp-Lys-Asn-Lys-Leu-Leu-Lys-Ser, where the underline indicates the different residue from the sequence cited in the reference; claim 75) that retains antimicrobial activity. Since neither the claim nor the specification clearly defines the term “mimetics thereof”, any substituted peptide which retains antimicrobial activity would meet the criteria of the claim.

In response, applicants indicate the peptides in ‘898 patent differ from the claimed antimicrobial peptides by having non-identical natural amino acid residues at several positions, while mimetics are “chemical structures derived from bioactive peptides which imitate natural molecules” as indicated in Goodman and Ro (pages 8-9 of the response). The response has been considered, however the argument is not found persuasive because Goodman and Ro defines “peptidomimetics” are “chemical structures derived from bioactive peptides which imitate natural molecules” (at paragraph bridging pages 804 and 805), as indicated in the paragraph 3, the mimetics include not only peptidomimetics but also other peptide-like structures, and the term has not been clearly defined in the specification.

5. Claims 67 and 68 are rejected under 35 U.S.C. 102(b) as anticipated by Kupsch *et al.* (The EMBO Journal 12, 641-650, 1993).

Kupsch *et al.* disclose one member of variable opacity (Opa) outer membrane proteins, OPA 65 has 236 amino acids and comprises a sequence of ARYRKWK, which is the same as the core sequence of the claimed invention (Fig. 4; see sequence match; claims 67 and 68). The

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OPA 65 protein would be expected to have antimicrobial activity because it contains the same core sequence as the claimed invention.

In response, applicants indicate claim 67 cites an isolated antimicrobial peptide having 13 to 74 amino acids, while Opa 65 has 236 amino acids (page 9 of the response). The response has been considered, however the argument is not found persuasive because claim 67 cites “An isolated antimicrobial peptide, comprising an amino acid sequence having 13 to 74 amino acids with a 7 amino acid core sequence”, which indicates the claimed peptide can have more than 13 to 74 amino acids because of the term “comprising”.

Conclusion

6. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

February 11, 2004

Christopher S. F. Low
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